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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/501,007

07/08/2004

Jacheon Lee

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23373 7590 11/06/2006

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EXAMINER

COVINGTON, RAYMOND K

ART UNIT

PAPER NUMBER

1625

DATE MAILED: 11/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/501,007

Applicant(s)

LEE ET AL.

Examiner

Raymond Covington

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>7/8/04</u> .  | 6) <input type="checkbox"/> Other: _____                                    |

### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoffman et al US 4,444,784 taken with Taoka et al US 6,331,641( US equivalent of WO 00/34264) in view of Dabora et al US 5,159,104

Hoffman et al teach preparing simvastatin from lovastatin by hydrolysis of the lactone ring using lithium hydroxide followed by relactonization, protecting the hydroxyl group on the lactone ring, then acylation with 2,2-dialkylbutyryl acid and deprotecting the lactone hydroxyl group. See, for example, columns 5-6, column 14 line 3, which teach using tertabutylammonium fluoride and example 3. Taoka et al teach an analogous process which uses lithium hydroxide or potassium hydroxide in a 1 to 10 ratio based on lovastatin with 2,2dimethylbutyryl chloride as the acylating agent. See, for example, column 2 lines 1-65, column 3 lines 25-30, column 4 lines 40-46, and column 5 lines 33-36. Dabora et al also teaches

analogous process for acylating using 2,2dimethylbutyryl acid or the 2,2dimethylbutyryl chloride derived therefrom. See, column 2 lines 5-15 and column 4 step c.

Hoffman et al differs from the claimed invention it uses lithium hydroxide instead of potassium hydroxide, it uses a dialkylbutyryl acid instead of a dialkylbutyryl bromide or chloride and , with respect to claim 5, it uses a tertabutylammonium fluoride instead of tertabutylammonium bromide.

However, the use of lithium hydroxide or potassium hydroxide in analogous processes is known as taught by Taoka et al. The use of dialkylbutyryl acid or dialkylbutyryl chloride is also known as taught by Taoka et al.

Further, it would have been obvious to one of ordinary skill in the art to use tertabutylammonium fluoride in lieu of tertabutylammonium bromide in light of their close structural similarities and their known use as acylating catalyst.

With respect to claim 8 it is well known in the art the acylation of lactones by conventional procedures involving temperatures of e.g. 100°C typically employ benzene as an inert organic solvent. Further, the use of Dean-Stark traps in processes involving benzene, particularly azeotropic separations, is also well known in the art . Note Wikipedia Dean-Stark apparatus. To apply these

techniques to other analogous latone acylation processes such as that recited in the claims would have been obvious as the results would not have been unexpected.

In view of the art as a whole the claimed invention would have been obvious as the results would not have been unexpected.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond Covington whose telephone number is (571) 272-0681. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie at telephone number (571) 272-0681.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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*Thomas McKenzie*

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